UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CITY OF HUNTINGTON,

Plaintiff,

v. Civil Action No. 3:17-cv-01362

AMERISOURCE BERGEN DRUG CORPORATION, et al.,

Defendants.

CABELL COUNTY COMMISSION,

Plaintiff, Consolidated case:

v. Civil Action No. 3:17-cv-01665

AMERISOURCE BERGEN DRUG CORPORATION, et al.,

Defendants.

PLAINTIFFS' MEMORANDUM OF LAW
IN OPPOSITION TO DEFENDANTS' MOTION
TO EXCLUDE EXPERT TESTIMONY
REGARDING DEFENDANTS' CORPORATE CONDUCT

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PRELIMINARY STATEMENT

Plaintiffs submit this memorandum in opposition to the motion of AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation ("Defendants") to exclude expert testimony regarding Defendants' corporate conduct pursuant to Federal Rule of Evidence 702 [ECF 1043-1044].

Defendants seek a blanket order excluding "all expert testimony" in three areas broadly (and vaguely) described as:

- 1. Testimony that restates factual information found in documents;
- 2. Testimony regarding Defendants' knowledge, intent, or state of mind; and
- 3. Testimony regarding Defendants' corporate ethics or responsibilities or duties.

Defendants motion should be denied. First, where, as here, the facts at issue are complex, the subject matter is highly technical, the relevant documents and other evidence are voluminous, and the time period at issue is lengthy, it will be helpful to the Court to have the guidance of experts to understand the significance of the evidence and the historical context of Defendants' acts and omissions. Second, Plaintiffs' experts do not speculate about Defendants' knowledge, intent, motives, or state of mind. Third, because Defendants' compliance with industry standards of care, statutory duties, and their own internal policies is at issue, and those standards, duties, and policies are not within the ordinary experience of lay persons, testimony from experts will be helpful to the Court.

FACTS

Defendants' motion seeks to exclude the testimony of the following experts:

Andrew Kolodny, M.D., a public health and addiction medicine expert, who opines that Defendants' conduct (i) was a substantial factor in causing the flood of prescription opioids into the United States, West Virginia, and the Huntington-Cabell Community, (ii) fell below any reasonable

standard of care, and (iii) was reckless (Expert Report of Andrew Kolodny, Plaintiffs' Appendix of Expert Reports [ECF 1097] Exhibit 6-a, at 2-3);¹

Anna Lembke, M.D., a physician specializing in addiction treatment, who opines that Defendants' collaboration with opioid manufacturers and pharmacies to promote sales of opioid pain pills (which included programs to give away free samples of opioids and opioid discount coupons and promotion of specific opioid products under the guise of education) increased the population of opioid users, the dose and duration of opioid use, and the risk of opioid misuse, addiction, dependence, and death (A7-a [ECF 1097-32] at 7-9);

Jakki Mohr, Ph.D., a professor of marketing, who opines about the numerous and highly sophisticated ways in which Defendants played a significant role in expanding and maintaining the opioid market (A9-a [ECF 1097-37] at 4-6);

Michael Siegel, M.D., a physician and professor of public health, who opines, *inter alia*, that the information Defendants had available to them was sufficient to establish that: (i) the volume of opioids they were distributing was inconsistent with public health; (ii) the oversupply of opioids was likely to result in serious, long lasting public health harm; and (iii) the oversupply was actually resulting in public health harm (A11-a [ECF 1097-41] at 9-10);

Gordon Smith, CH.B., a physician and epidemiologist, who opines, on the basis of state and national data that: (i) prescription opioids were the primary cause of death in West Virginia in the years 2001 through 2011; (ii) even as heroin and illicit fentanyl mortality has increased in more recent years, prescription opioids have continued to pay a major role in the opioid epidemic in West Virginia; and (iii) until 1999, West Virginia had experienced a low and stable rate of drug overdose mortality for a least 20 years. (A12-a [ECF 1097-42] at 4-5); and

¹ Defendants' Exhibit 2 is only a portion of Dr. Kolodny's report; his complete report is reproduced in Plaintiffs' Appendix of Expert Reports as Exhibit 6-a [ECF 1097-26]. Citations to exhibits in the Appendix hereinafter appear as "A[exhibit number]."

David Courtwright, Ph.D., an internationally recognized authority on the history of drug use and drug policy, an area in which he has published since 1978, who explains, *inter alia*, how manufacturers undermined narcotic conservatism—the principal barrier to expanding the market for their opioid products—with the help of marketing and information services supplied by Defendants, who played more than a distributional role in the prescription opioid addiction and overdose crises. (A3-a [ECF 1097-14] at 6-8).

LEGAL STANDARD

The legal standards applicable to this motion are set forth in Plaintiffs' Memorandum in Opposition to Exclude the Expert Testimony of Andrew Kolodny, Dkt. #1099, at 4-7, to which the Court is respectfully referred. Defendants' motion does not challenge the qualifications of the experts, the reliability of their principles and methods, or the sufficiency of the facts or data on which their opinions are based. Rather, Defendants' motion is based entirely on their contention that the expert testimony at issue will not "help the trier of fact." Fed. R. Evid. 702. "This condition goes primarily to relevance." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591 (1993). As we demonstrate below, the testimony Defendants seek to exclude is relevant and will be helpful to the trier of fact.

ARGUMENT

I. PLAINTIFFS' EXPERTS DO NOT IMPROPERLY OPINE REGARDING DEFENDANTS' CORPORATE CONDUCT

Defendants' application is styled as a motion "to exclude expert testimony regarding Defendants' corporate conduct." That is a misnomer, for there exists no rule against experts testifying about a corporate defendant's conduct—especially when that defendant's conduct is at issue. Plaintiffs address below the actual legal principles that are applied in the cases cited by Defendants.

A. Experts May Summarize the Facts and Evidence on Which They Rely and May Do So in Narrative Form

Defendants argue that the testimony of the experts whom they challenge "merely regurgitates factual information that is better presented directly to the [trier of fact] rather than through the testimony of an expert witness." Memorandum of Law in Support of Defendants' Motion [ECF 1044] ("Def. Mem.") at 4 (internal quotation marks omitted). Defendants' argument, however, is founded on the false premise that there is blanket rule against experts providing narrative summaries or explanations of evidence. There is no such rule.

Fed. R. Evid. 611(a) provides, "[t]he court should exercise reasonable control over the mode and order of examining witnesses and presenting evidence so as to: (1) make those procedures effective for determining the truth [and] (2) avoid wasting time" The Fourth Circuit has held that "Rule 611(a) can be used as a basis for the admission of summary testimony when the testimony aids in ascertaining the truth. ... The complexity and length of the case as well as the numbers of witnesses and exhibits are considered in making [this] determination." *United States v. Rollack*, 570 F. App'x 267, 277 (4th Cir. 2014) (citations and internal quotation marks omitted). *See, e.g., United States v. Janati*, 374 F.3d 263, 275 (4th Cir. 2004); *United States v. Barrie*, No. CRIM. PWG-14-0006, 2014 WL 7014485, at *5 (D. Md. Dec. 10, 2014), *aff'd*, 629 F. App'x 541 (4th Cir. 2015).

Indeed, the use of summary experts is commonplace in this Circuit. "[W]hen the legal regime is complex and the judge determines that the witness' testimony would be helpful in explaining it . . . the testimony may be admitted." *United States v. Offill*, 666 F.3d 168, 175 (4th Cir. 2011) (securities law expert); *accord United States v. Duarte*, 581 F. App'x 254, 257 (4th Cir. 2014) (money laundering expert). *See also United States v. Pree*, 408 F.3d 855, 869-70 (7th Cir. 2005) (IRS agent testified as expert summary witness).

Nor is there any general rule that prevents experts from discussing the evidence on which their opinions are based in the form of a narrative. Expert narrative testimony is entirely permissible where, as here, the documents and other information the expert is reviewing are complicated, voluminous, or involve scientific or technical data and such narrative summary would be helpful to the trier of fact in understanding the evidence. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 2:14-MN-02502-RMG, 2016 WL 2940784, at *4 (D.S.C. May 6, 2016); *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, No. 3:11-MD-2244-K, 2014 WL 3557345, at *7 (N.D. Tex. July 18, 2014); *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011).

To describe testimony as a "narrative" is the beginning not the end of analysis. The distinction between a *permissible* narrative and an *impermissible* one was explained by the court in *In re Welding Fume Product Liability Litigation*, 2005 WL 1868046 at *17 (N.D. Ohio Aug. 8, 2005):

a "narrative" by an expert is not automatically inadmissible; it is only when ... the narrative is purely "a repetition of the factual allegations in plaintiffs' complaint," involving "nothing technical or scientific," that a court might find the expert testimony unhelpful, because the expert is providing only "simple inferences drawn from uncomplicated facts."

Id. (citation omitted). Where, as here, "the great majority of the documents and articles that [the expert] is reviewing and comparing are complicated, and the inferences those documents may or may not support are not at all simple," a qualified expert can apply expertise to help "the trier of fact to better understand what the documents do (and don't) mean, and thus, what the defendants did (or didn't) know." *Id.* at *17.

Indeed, the expertise of an historian has often been found useful to assist the trier of fact in understanding a lengthy historical record. For example, in the tobacco litigation, the defendants

were allowed to offer the testimony of an historian who relied on a wide variety of documents, synthesized the documents, and opined that between 1947 and 1969 there was widespread common knowledge among ordinary people that cigarette smoking could cause serious life-threatening diseases. *Waterhouse v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 432, 436 (D. Md. 2005), *aff'd*, 162 F. App'x 231 (4th Cir. 2006). *See also Walden v. City of Chicago*, 755 F. Supp. 2d 942, 948-49 (N.D. Ill. 2010) ("researcher and doctoral candidate in history," who had conducted an historical study regarding the policies and practices of the Chicago Police Department, allowed to testify that "all the available evidence points to the existence of a historic pattern of coercive interrogations and illegal detentions that represented a *de facto* policy and practice of the Chicago Police Department in existence in 1952 at the time of [the plaintiff's] arrest and alleged mistreatment"). While an expert must do more than simply construct a factual narrative based on record evidence, an expert can certainly testify as to the facts relied upon in forming his opinions so long as they are relevant and not cumulative. *See Wells v. Allergan, Inc.*, No. CIV-12-973-C, 2013 WL 7208221 at *2 (W.D. Okla. Feb. 4, 2013).

The cases cited by Defendants are plainly distinguishable. In *Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-CV-00837, 2012 WL 524442, (S.D.W. Va. Feb. 15, 2012), the court held that an expert could not testify that "a stapler without staples is defective" because that opinion did "not draw on any specialized knowledge, education, or experience" but rather was merely "a matter of common sense." *Id.* at *8. In *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842 (S.D.W. Va. July 8, 2011), the court exercised its discretion to exclude summary evidence in that case because, in particular the circumstances of that case, "the jury is more than capable of reading and summarizing the documents [at issue] on its own." *Id.* at *7.

Defendants' argument also conflates the experts' Rule 26 reports with their trial testimony.

The reports of the challenged experts contain a detailed recitation of the facts and information

underlying their opinions. There is a good reason for that. Rule 26 requires that expert reports include not only "(i) a complete statement of all opinions the witness will express and the basis and reasons for them," Fed. R. Civ. P. 26(a)(2)(B)(i), but also a statement of "the facts or data considered by the [expert] witness in forming [the opinions]." Fed. R. Civ. P. 26(a)(2)(B)(ii). Experts are not, however, required to engage in such a detailed recitation at trial, and there is no reason to imagine that Plaintiffs' experts will do so.

The extent to which the underlying evidence can or should be admitted through Plaintiffs' experts, or though other evidence, such as testimony of other witnesses or the admission of the documents cited in the reports, and the extent to which summaries of some portions of this evidence by the experts may assist the trier of fact in understanding both the evidence itself and the experts' opinions based on that evidence, does not implicate this Court's gate-keeping role under *Daubert*. It is, rather, a matter of this Court's discretion over the presentation of evidence at trial. Fed. R. Evid. 611(a).

Defendants cite Judge Goodwin's decision in *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), but they neglect to mention that Judge Goodwin refused to enter an order barring narrative testimony, saying instead that he would exercise his discretion—at trial—to cut off unduly lengthy factual narrative. 948 F. Supp. at 646. *Accord In re Lipitor*, 2016 WL 2940784, at *4. *See also United States v. Osum*, 943 F.2d 1394, 1405 (5th Cir. 1991). This Court should do the same and reserve until trial any ruling on objections to narrative or summary testimony.

1. Dr. Kolodny May Testify about the Factual Basis for His Opinions

Defendants complain that Dr. Kolodny "spends four pages of his Report simply quoting from a 2018 congressional report, without additional analysis." Def. Mem. at 4, citing A6-a at 84-87. But Dr. Kolodny's report is not his testimony. There is no reason to believe that in his testimony a trial Dr. Kolodny will merely quote from documents without analysis.

Defendants also complain that Dr. Kolodny "copies and pastes statistics on distributors' distribution numbers directly from the report of Plaintiffs' expert Dr. Craig McCann without further analysis," Def. Mem. at 4, citing A6-a at 24-30, and that he "offers lengthy narrative summaries of selected internal company documents regarding promotional materials." Def. Mem. at 4, citing A6-a at 40-48. Here again, Defendants' argument is based on the unfounded notion that Dr. Kolodny intends to read his report to the trier of fact.

Defendants seek to bar Dr. Kolodny from "opining" that distributors sell to the nation's largest chain pharmacies on the ground that he fails to explain "why that is relevant." Def. Mem. at 4, citing A6-a at 70[sic]-77. But the fact that distributors sell to large chain pharmacies is an undisputed fact, not an opinion, and the relevance of that fact is made plain in the report: "Defendants also continued their opioid business relationships with national retail pharmacy chains even after each had been cited for breaking the law and paid fines." A6-a at 74. To the extent Defendants require a further explanation of relevance, they are free to ask Dr. Kolodny to provide it on cross-examination.²

Finally, Defendants seek to bar Dr. Kolodny from mentioning in his testimony that Defendants were "cited for breaking the law" by quoting or referencing civil settlement agreements. Def. Mem. at 4, citing A6-a at 78, 80-81. Defendants, however, do not dispute that the documents constitute evidence on which an expert may reasonably rely. In these circumstances, there is no reason why Dr. Kolodny should not be allowed to rely on them in his testimony.

² Dr. Kolodny testified at the trial of *Oklahoma v. Purdue Pharma LP*, and the trial judge evidently found his testimony relevant and helpful, for the court cited his testimony in the final judgment thirty-six times. *Oklahoma v. Purdue Pharma LP*, No. CJ-2017-816, 2019 WL 4019929 (Okl. Dist. Aug. 26, 2019).

2. Dr. Siegel May Testify about the Factual Basis for His Opinions

Defendants complain that "Dr. Siegel offers an extensive narrative summary of internal company documents, without further analysis, for the purely factual proposition that 'information was available' to Defendants regarding opioid abuse." Def. Mem. at 5, citing A11-a at 82-99. It is unclear, however, why Defendants think that is objectionable. What is wrong with an expert providing in his report "extensive" support for the facts on which he relies? Indeed, had he failed to provide such support, Defendants would no doubt contend that the opinion was insufficiently reliable because of the lack of evidence cited in support of it.

According to Defendants, Dr. Siegel improperly summarizes and quotes from documents for the proposition that there were "allegations" by the DEA against McKesson. Def. Mem. at 4-5, citing A11-a at 100. Defendants, however, have mischaracterized what Dr. Siegel said in his report, to wit:

In 2017, McKesson made certain admissions of fact under a settlement agreement with the DEA in which it acknowledged a failure to maintain effective controls against opioid diversion and agreed to pay a settlement amount of \$150 million. Specifically: "McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5)."

A11-a at 100 (emphasis added). Thus, Dr. Siegel was not improperly summarizing mere *allegations*; he was—quite permissibly—quoting McKesson's own *admissions* of relevant wrongdoing.

3. Drs. Lembke and Mohr May Testify about the Factual Bases for Their Opinions

Defendants complain that Drs. Lembke and Mohr spend many pages summarizing and quoting from Defendants' internal documents. As with the experts discussed above, there is nothing improper about these experts summarizing and quoting in their reports the evidence they rely on

(indeed, they are required to do so), and there is no reason to suppose that they will testify at trial as if they were reading their reports.

4. Dr. Courtwright May Testify about the Factual Basis for His Opinions

After attacking Plaintiffs' other experts for excessively quoting from and referring to underlying documents in their Rule 26 reports, Defendants attack Dr. Courtwright because they say he fails to cite underlying documents every time he makes a factual statement. Def. Mem. at 5, citing A3-a at 78 & 103. But this is an altogether different objection than the "helpfulness" objection upon which Defendants' motion is purportedly based. Defendants have not objected to the adequacy of Dr. Courtwright's report or its compliance with Rule 26. Nor have they sought to exclude Dr. Courtwright's testimony as lacking an adequate factual basis. They have not done so because they know that Dr. Courtwright's list of materials considered provides an ample basis for the facts on which he relies. Any suggestion that Dr. Courtwright's testimony would be unhelpful is entirely without merit. The expertise of an internationally recognized authority on the history of drug use and drug policy will be useful to assist the trier of fact in understanding a complicated historical record. See Waterhouse v. R.J. Reynolds Tobacco Co., 368 F. Supp. 2d 432, 436 (D. Md. 2005), aff'd, 162 F. App'x 231 (4th Cir. 2006). Defendants offer no reason to think otherwise.

B. Plaintiffs' Experts May Offer Testimony Relevant to Defendants' Knowledge, Intent, or State of Mind

Plaintiffs acknowledge that their experts may not engage in speculation regarding Defendants' state of mind. *In re Lipitor*, 2016 WL 2940784, at *4 n.3; *In re Trasylol Prod. Liab. Litig.*, 709 F. Supp. 2d 1323, 1338 (S.D. Fla. 2010). In expressing their opinions and explaining the factual basis for their opinions, however, it is not improper for an expert to make objective observations pertaining to the knowledge of a party, if this observation is supported by the record and the expert's analysis. *See In re Actos*, 2014 WL 120973 at * 16. For example, an expert may

testify about what a defendant "knew' in the sense of what information was in its possession." *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 480 (S.D.N.Y. 2016). Likewise, expert testimony about intent may be proper if based on information "set forth in documents or grounded in specific, objectively knowable facts." *Id.*; *In re Levaquin Prods. Liab. Litig.*, No. 08-md-1943, 2011 WL 6888533 at *2 (D. Minn. Dec. 29, 2011). Simply put, an expert may opine that a defendant "knew" or "intended" something when the evidence objectively demonstrates that knowledge or intent.

While Defendants' motion seeks a blanket ruling regarding six of Plaintiffs' experts, the only specific testimony they claim to be objectionable is that of Dr. Kolodny, whom they accuse of having impermissibly imputed knowledge and intent to Defendants. They cite as "a particularly clear example," Def. Mem. at 6, Dr. Kolodny's statement that McKesson "was more interested in profits than in having meaningful systems in place to prevent diversion." A6-a at 62. They argue that Dr. Kolodny has no factual basis for his statement. Def. Mem. at 7. But Defendants have taken Dr. Kolodny's statement out of context and divorced it from its factual foundation. What Dr. Kolodny actually said was, "McKesson made clear, however, it was more interested in profits than in having meaningful systems in place to prevent diversion, stating that '[w]e are in the business to sell product. If we could produce a report ... that warned as customers approach to the threshold, say at 85% of their 10,000 dosages, work could begin on justifying an increase in threshold prior to any lost sales." A6-a at 62 (bold in original), quoting MCKMDL00543971 at 972. Thus, Dr. Kolodny's statement was not speculation about McKesson's state of mind; it was a well-founded factual observation about how McKesson prioritized profit over preventing diversion.

Defendants also complain about Dr. Kolodny's statement that "Defendants chose to ignore Purdue's greed and recklessness," A6-a at 70, as if he had no basis for that statement. To the contrary, his statement was well founded:

In 2003, the federal government issued a report detailing Purdue's improper marketing of OxyContin. Had the Defendants ceased supplying OxyContin after the release of the report, as a prudent distributor of narcotics should have done, the Opioid Epidemic might have been brought to an early end and a strong message to deter other opioid manufacturers from improper marketing would have been sent. Instead, the Defendants chose to ignore Purdue's greed and recklessness and continued to do business with the company [and] increase sales. Even after Purdue and other opioid manufacturers were criminally convicted, the Defendants continued to do business with Purdue, helped it promote its products and joined Purdue in an effort to preserve the status quo by deceiving regulators, policymakers, health professionals and the public.

Id. (footnote omitted). As is clear when Dr. Kolodny's statement is read in context, his statement about greed and recklessness was not a comment on *Defendants*' state of mind; it was a well-founded comment on Purdue's behavior. Insofar as this paragraph related to Defendants, it was not an opinion about their state of mind; it was a factual statement about how they chose to continue to do business with a company whose criminal misconduct—with respect to the products at issue—was a matter of highly publicized common knowledge.

Similarly, Defendants criticize Dr. Kolodny's statement that Defendants decided to "team up with known criminals to break the law," *id.* at 72, as if that were was an unfounded opinion about their state of mind. To the contrary, it was a statement of well-founded fact:

Meetings with this known felon [Purdue] focused on "communication and cooperation," "collaborat[ion]...on issues about [Purdue] product(s)," a "collaborative effort," "maximiz[ing] [their] shared objectives," and helping the opioid industry protect itself from "over-zealous regulators." McKesson endorsed this collaborative effort in the years following Purdue's conviction and stated that "[it] was in 100% agreement with Purdue and . . . recognized that this collaborative effort was the right thing to do." As McKesson stated, "we ultimately protect ourselves."

"Protecting themselves," meant that this time Defendants would team up with known criminals to break the law in a different way, this time through circumventing the protections designed to prevent oversupply and diversion. Internal documents show Purdue telling McKesson that "Joe Rannazzisi [of the DEA] is publicly stating that 'Manufacturers are now sending letters to their wholesale distributor consumers warning them of their due diligence obligations. . .,' our Purdue Team does not and will not operate in that manner." Similarly, Purdue wrote to Cardinal stating that "[w]e should gang up on DEA." Defendants did not reject Purdue's blatant proposals

to break the law, they did not stop doing business with this repeated law breaker and they did not turn Purdue in to law enforcement. Instead, they embraced the plan of circumventing regulations and defying law enforcement, putting the public health and safety directly at risk to "protect themselves."

Id. at 71-72 (footnoted omitted).

The other examples Defendants cite are likewise based on taking individual phrases and separating them from their factual support.

- Dr. Kolodny's statement that "[h]ad the Defendants operated as prudent distributors of narcotic drugs they would not have turned a blind eye to the overt wrongdoing and criminal behavior of their partners in the supply chain," *id.* at 78, comes at the end of an eight-page discussion of the evidence that shows that Defendants continued to do business with admitted lawbreakers who had lied in promoting prescription opioids and who had been cited for breaking laws governing opioid distribution. *Id.* at 70-78.
- His statements that "[e]ach time the DEA caught and cited the Defendants, however, the Defendants did not take it as an opportunity to increase safety and compliance with the CSA, but rather continued business as usual" and "numerous internal documents evidence how Defendants made conscious decisions to ignore the law," *id.* at 83, are followed by specific examples that back up his factual statement about their conduct. *Id.* at 83-88.
- His statement that "McKesson knew all along that its representations about improvements to its anti-diversion program were false" is immediately followed by the specific evidence that supports his statement. *Id.* at 92.
- His statement that "[a]pparently, the Defendants believe their expensive PR campaigns have worked, at least in part, seeing 'progress' in the press coverage in 2017" is supported by his citation to an internal Amerisource email discussing a ProPublica story about distributors "Turning Blind Eye in Opioid Epidemic," and noting that while tone was negative, information from the Healthcare Distribution Alliance (Defendants' trade association) was included in the story that suggested DEA was partly at fault). *Id.* at 104.

C. Plaintiffs' Experts Do Not Offer Personal Opinions Regarding Ethics

Defendants rely on *In re Rezulin Products Liab. Litig.*, 309 F. Supp. 2d 531, 543-45 (S.D.N.Y. 2004)], for the premise that ethics opinions are irrelevant and accordingly unhelpful in matters of product liability and marketing claims. 309 F. Supp. 2d at 544 (precluding opinions on ethical standards of pharmaceutical companies in suit concerning manufacturing, labeling, and

marketing of product). However, "expert testimony regarding applicable ethical standards may be helpful in cases where, as here, one party's duties to another are in question through for example, negligence claims, or if the standard of care of alleged negligence is not within the ordinary experience of lay persons." *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, No. 3:11-MD-2244-K, 2016 WL 6271474, at *5 (N.D. Tex. Jan. 5, 2016). Therefore, expert "testimony on compliance with industry standards and Defendants' own internal policies" has been held "sufficiently relevant and helpful to the jury to be admitted." *Id. See Garcia v. Columbia Med. Ctr. of Sherman*, 996 F. Supp. 617, 627 (E.D. Tex. 1998) ("testimony regarding ethical duties may be useful in informing the jury about the accepted standards of medical care which a reasonable health care provider would follow and in helping the jury to determine whether Defendants deviated from those standards").

1. Dr. Kolodny Does Not Offer Any Personal Opinion on Ethics or Morality

Defendants object to several of the conclusions Dr. Kolodny offers in his report as being ethics opinions, but nowhere in that report is there the slightest suggestion that his conclusions are based on ethical standards. To the contrary, he makes clear that his opinions are based on "Defendants' clear duties to design adequate systems to prevent diversion," *id.* at 63, their "duties under the law to stop abuse and diversion of opioids," *id.* at 91, and their "compliance with their CSA duties." *Id.* at 96. Indeed, he specifically describes those duties in his report:

To be granted the privilege of selling dangerous scheduled narcotics, each distributor must comply with the Controlled Substances Act ("CSA"). See 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). As McKesson recognized in one internal presentation, distributors have "great power" within this system, but "with great power comes great responsibility." Under the CSA, each distributor owes a duty to protect the public health and safety by maintaining *effective* controls against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970](emphasis added). The regulations specifically require all distributors to report suspicious orders of controlled substances, in addition to the statutory responsibility to exercise due diligence to avoid filling suspicious orders.

A6-a at 78 (footnotes omitted; emphasis in original).

In addition to relying on Defendants' duties under the CSA, Dr. Kolodny also relies on their duty to refrain from participating with opioid manufacturers in a fraudulent marketing scheme. While he does not cite any legal authorities or articulate any black letter legal principles as he does with their CSA duties, it is perfectly clear that his opinions are not predicated solely on his personal standards of ethics or morality but rather are firmly rooted in the normal legal duty that everyone has to refrain from participating in fraud.

Turning to the specific examples cited by Defendants, none represents a personal opinion about ethics or morality:

- When Dr. Kolodny opines that Defendants were "reckless and irresponsible," A6-a at 39, he was referring to how they had participated in "opioid drug maker's marketing and misinformation campaign that drove the dramatic increase in demand for opioids ... that caused overexposure of the population to dangerous and addictive pharmaceutical products." *Id*.
- When he opines that they "recklessly ignored" information, *id.* at 59, he was referring to the many "significant warning signs that should have alerted Defendants things were going dangerously wrong with the opioids they were supplying," *id.* at 53; 53-59, and that, as a result, "Defendants failed in their obligation as DEA registrants." *Id.* at 59.
- When he states that "[i]n blatant disregard for public health and safety, including that in the Huntington-Cabell Community, the Defendants refused to take responsibility for the epidemic, even today, and even tried to shift blame to others, including the people they helped addict to opioids," *id.* at 102, he was not offering "his own view of corporate conduct," Def. Mem. at 8; rather, he was talking about how Defendants have offered false exculpatory "excuses for not following their compliance obligations." *Id.* at 105.
- Contrary to Defendants' mischaracterization, when Dr. Kolodny states, as a fact, that "Defendants continued to do business with admitted lawbreakers who had lied in promoting prescription opioids and who had been cited for breaking laws governing opioid distribution," *id.* at 70; *see also id.* at 3, he did not "opine[] that it was wrong," as a matter of ethics or morality, for Defendants to do so. Def. Mem. at 8. Rather, he was opining that Defendants' actions were a substantial cause of the opioid epidemic. *Id.* at 3, 37.

- Defendant's suggest that Dr. Kolodny was offering an ethics opinion when he stated that it was "utterly reckless and unreasonable for Defendants to continue supplying opioid products," id. at 65, but Defendants have failed to quote his full statement, which is: "Nevertheless, if Defendants found it impossible to design an adequate system to prevent opioids diversion because of the obstacles they identify, then it was utterly reckless and unreasonable for Defendants to continue supplying opioid products and supplying them in the amounts they did." Id. Thus, the statement at issue is firmly grounded in Defendant's legal obligations.
- Finally, Defendants' selective editing cannot convert Dr. Kolodny's opinions about what they "should have done," into an ethics opinion. In the passage Defendants cite, Dr. Kolodny was expressing a *causation* opinion:

Had the Defendants operated as prudent distributors of narcotic drugs they would not have turned a blind eye to the overt wrongdoing and criminal behavior of their partners in the supply chain. As the largest distributors of pharmaceutical products in the country, had the Defendants made clear to the industry that improper marketing and retailing of narcotics would not be tolerated, wrongdoing by their business partners would have ceased, millions of cases of opioid addiction might have been prevented and thousands of needless deaths prevented.

Id. at 78.

2. Dr. Siegel Does Not Offer Any Personal Opinion on Ethics or Morality

Dr. Siegel does not offer any personal opinion on ethics or morality. What he describes in his opinion is a *standard of care*:

Pharmaceutical distributors have a well-recognized public health responsibility to generally and specifically protect the health of the public—to protect the public from the severe health consequences associated with oversupply of drugs. This responsibility derives, in part, from the fact that pharmaceutical distributors are part of the health care industry, whose underlying mission and responsibility is the protection and improvement of the public's health.

A11-a at 19. In making that statement, Dr. Siegel does not rely on some "amorphous" personal opinion about ethics or morality. He relies on (i) literature in the Public Health field, *id.*, (ii) the World Health Organization, *id.* at 20, (iii) The Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services, *id.*, (iv) statements of members of the pharmaceutical industry, including pharmaceutical distributors, including admissions by Defendants themselves, *id.*

at 21-32, (v) the Controlled Substances Act, and (vi) the law of West Virginia. *Id.* at 23, 31-21 & n.62. His opinions are thus well grounded in statutory, common law, and industry standards of care.

Contrary to Defendants' argument, Dr. Siegel never "acknowledges" that his standard of responsibility goes beyond Defendants' relevant legal responsibilities. Def. Mem. at 8, citing A11-a at 31-32. What he actually said was:

McKesson has made it clear that it has a responsibility that goes beyond merely its statutory and regulatory duties; that is, that it owes a responsibility to the general public, which is essentially a public health responsibility. In his deposition testimony, Nathan Hartle—McKesson's vice president of regulatory affairs and compliance from 2014—acknowledged (i.e., answered "yes") to the question: "So your answer is, yes, aside from the statutory and regulatory provisions, McKesson acknowledges that it owes a responsibility to the general public to prevent diversion of controlled substances and opium pills into the illicit market?"

Id. at 31. Thus, it was McKesson who acknowledged that its relevant duties are not limited to its statutory duties under the CSA—as, indeed, they are not.

3. Dr. Smith Does Not Offer Any Personal Opinion on Ethics or Morality

Defendants argue that Dr. Smith seeks to offer an improper ethics opinion because he agrees that "the industry's credibility is near zero." Def. Mem. at 8, citing Def. Ex. 8, Smith Dep., Sept. 22, 2020 at 102:1-10. Defendants' argument, however, is based on a distortion of both Dr. Smith's causation opinion and his deposition testimony.

What he said in his report was:

The more I work on opioids in West Virginia, the more I concur with [a] Task Force conclusion that "The opioid crisis can be directly tied to practices adopted and encouraged by opioid manufacturers and distributors. As such, the industry's credibility is near zero and major changes in its practices are essential."

A12-a at 17-18. Thus, the gist of the opinion in his report was that the manufacturers and distributors caused the opioid crisis and that changes in those practices are needed. The statement in the Task Force report about credibility was not the point of the quote; nor was that the point of Dr. Smith's adoption of it. At deposition it was clear that Dr. Smith was not offering an opinion about

Defendants' credibility: "Q. But you don't have an understanding of what those authors meant by 'the industry's credibility.' Is that right? A. Yes" Def. Ex. 8, Smith Dep., Sept. 22, 2020 at 102:1-10. Thus, Defendants' argument that Dr. Smith intends to offer personal opinions about ethics or morality finds no support in the record.

- 4. Dr. Mohr's Opinions Are Securely Moored in Law and Industry Standards

 Defendants ague that "Dr. Mohr provides opinions on her view of corporate ethics,
 unmoored from any legal requirements." Def. Mem. at 8. They object to the following statements:
 - "[a]ny company that participates in marketing a product . . . has a duty to do so without causing harm." A9-a at 6.
 - there is a "basic duty" to "avoi[d] situations where one's professional interests conflict with society's interests." *Id.* at 13.
 - there is a "higher duty" in selling "potentially harmful products to a vulnerable population." *Id.* at 15.

Contrary to Defendants' argument, those statements are not based solely on Dr. Mohr's personal standards of ethics or morality. Dr. Mohr explains that "marketing professionals rely on the code of conduct found in the American Marketing Association's Code of Ethics." *Id.* at 13 & Schedule 3. She also relies on The Code of Ethics for the Public Relations Society of America, *id.* at 13 & Schedule 4, the Federal Trade Commission's Endorsement Guidelines, *id.* at 14, and the World Health Organization. *Id.* at 14 & n.36. Thus, her statements are based on industry standards and not just personal standards.

Defendants argue that Dr. Mohr's opinion that those who sell dangerous drugs have heightened standards of conduct is "unmoored from any legal requirements," Def. Mem. at 8, but that is not so. While Dr. Mohr, a marketing expert, does not cite legal authorities (and Defendants would no doubt contend she was offering an improper legal opinion had she done so), Defendants cannot gainsay that the common law courts of West Virginia and elsewhere have long recognized

that those who deal in dangerous drugs *are* held to a heightened duty of care. *Peters v. Johnson*, 50 W. Va. 644, 41 S.E. 190, 191 (1902), citing the leading case of *Thomas v. Winchester*, 6 N.Y. 397, 410 (1852). The industry standards on which Dr. Mohr relies are entirely consistent with that heightened common law duty. For example, the Code of Practice for the International Federation of Pharmaceutical Manufacturers and Associations acknowledges that "[w]e ... hold ourselves to higher ethical standards than other industries." Similarly, the Pharmaceutical Research and Manufacturers of America acknowledges, "we are committed to following the highest ethical standards as well as all legal requirements." A9-a. at 15. Here, as in *Garcia*, "testimony regarding ethical duties may be useful in informing the jury about the accepted standards of ... care." 996 F. Supp. at 627.

II. DEFENDANTS FAIL TO IDENTIFY SPECIFIC OPINIONS TO EXCLUDE

Motions *in limine* to exclude "broad categor[ies] of information" are improper because "the Court cannot rule in a vacuum." *In re Cathode Ray Tube (CRT) Antitrust Litig.*, 2016 WL 7803893, at *2 (N.D. Cal. Nov. 15, 2016). This is particularly true for motions to exclude expert opinions. Without "the specific content and nature of the opinions and testimony" at issue, the court cannot reasonably be asked to determine which opinions, if any, are excludable and which are not. *AMX Corp. v. Pilote Films*, 2007 WL 2428940, at *2 (N.D. Tex. Aug. 27, 2007). *Accord Mabrey v. Wizard Fisheries, Inc.*, 2007 WL 1876540, at *1 (W.D. Wash. June 27, 2007) ("[w]ithout offering a specific opinion to be excluded under this rule, the Court cannot preemptively grant defendant's motion *in limine*"); *In re Ethicon, Inc.*, 2016 WL 4473449, at *3 (S.D.W. Va. Aug. 24, 2016) ("[n]or can I assess the plaintiffs' general reliability concerns without more detail as to the testimony they wish to exclude").

While Defendants identify many of the specific opinions they seek to exclude, they also seek a blanket order excluding "all expert testimony" by in six different witnesses in three expansively

described categories. To the extent that Defendants' seek such a broad general ruling, without identifying specific opinions they ask the Court to exclude, their motion should be denied.

Conclusion

For the foregoing reasons, this Court should deny in its entirety Defendants' motion to exclude expert testimony regarding Defendants' corporate conduct.

Dated: October 23, 2020

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I certify that on October 23, 2020, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. This

filing will also be served on all parties by email to:

<u>Track2OpioidDefendants@ReedSmith.com</u> and <u>mdl2804discovery@motleyrice.com</u>.

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